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EXAMINER

MALLARI, PATRICIA C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3736

DATE MAILED: 02/10/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,345

Applicant(s)

KAN, JIE

Examiner

Patricia C. Mallari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-9,12-14,17,18,20-29 and 32 is/are rejected.
- 7) ☒ Claim(s) 3-5,10,11,15,16,19,30 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Objections

Claim 1 is objected to because of the following informalities: on line 2 of the claim “a human wrist” should be replaced with “a human wrist of a patient”. Appropriate correction is required.

Claim 2 is objected to because of the following informalities: on lines 3-4 of the claim, “the hand” should be replaced with “the hand attached to the wrist”. Appropriate correction is required.

Claim 3 is objected to because of the following informalities:
on line 4 of the claim “the forearm” should be replaced with “the forearm attached to the wrist”;
on line 5 of the claim “of body” should be replaced with “of the patient’s body”.
Appropriate correction is required.

Claim 4 is objected to because of the following informalities:
on line 3 of the claim, “the hand” should be replaced with “the hand attached to the wrist”;
on line 4 of the claim, “the palm” should be replaced with “the palm of the hand”;
on line 5 of the claim “the central line” should be replaced with “a central line”;
on line 6 of the claim “the little finger” should be replaced with “the little finger of the hand”. Appropriate correction is required.

Claim 5 is objected to because of the following informalities:
on line 3 of the claim “the hand” should be replaced with “the hand attached to the wrist”;

on line 4 of the claim "a forearm" should be replaced with "the forearm attached to the wrist";

on line 5 of the claim "of body" should be replaced with "of the patient's body";
and on line 8 of the claim "the little finger" should be replaced with "the little finger of the hand". Appropriate correction is required.

Claim 9 is objected to because of the following informalities:

on lines 1-2 of step a of the claim "said this column" should be replaced with "said selected column";

on lines 1-2 of step b of the claim "said this measuring site" should be replaced with "said optimal site";

on line 3 of step b of the claim, "possess" should be replaced with "possesses";
on line 10 of step b of the claim, "this measuring site" should be replaced with "the optimal site". Appropriate correction is required.

Claim 18 is objected to because of the following informalities:

on line 5 of the claim "a least a" should be replaced with "at least a";
on line 6 of the claim "a hand" should be replaced with "a hand attached to the wrist", "wrist" should be replaced with "the wrist" and "forearm" should be replaced with "the forearm attached to the wrist";

on line 7 of the claim, "non-extensible" should be replaced with "a non-extensible". Appropriate correction is required.

Claim 19 is objected to because of the following informalities: on line 9 of the claim, "the little finger" should be replaced with "the little finger of the hand"; on lines 7-8

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of the claim "by non-extensible device" should be replaced with "by a non-extensible device". Appropriate correction is required.

Claim 20 is objected to because of the following informalities: on line 2 of the claim "a part covering the dorsal side" should be replaced with "a part adapted to cover the dorsal side". Appropriate correction is required.

Claim 21 is objected to because of the following informalities:

on line 3 of the claim, "bladder;" should be replaced with "bladder," and "possess" should be replaced with "comprises";

on line 4 of the claim "which faces the skin" should be replaced with "adapted to face the skin" and "wrist;" should be replaced with "wrist,";

on line 5 of the claim, "made with" should be replaced with "made of";

on line 6 of the claim, "wrist;" should be replaced with "wrist," and "elasticity, and" should be replaced with "elasticity and". Appropriate correction is required.

Claim 23 is objected to because of the following informalities: on line 6 of the claim "a midpoint of" should be replaced with "a midpoint between". Appropriate correction is required.

Claim 27 is objected to because of the following informalities: on line 3 of the claim "position" should be replaced with "a position". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 21, 24-27, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "the two external pressure values" on line 8 of step b. There is insufficient antecedent basis for this limitation in the claim. Additionally, claim 9 recites the limitation "the maximum amplitude point" on lines 8-9 of step b) of the claim. It is unclear to which of the maximum amplitude points, as claimed on lines 3-4 of step a) of claim 9 and line 9 of step a of claim 9, this limitation refers.

Claim 21 recites the limitation "a material with higher rigidity" on line 6 of the claim. "Higher" is a comparative term; the claim is indefinite because there is no limit with which to compare the rigidity of the material in order to determine whether the material is of "higher" rigidity.

Claim 24 recites the limitation "said compressing wall" on lines 11 and 13 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 32 recites the limitation " the measure ulnar artery blood pressure" on line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-8, 17, 21, and 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hon (WO 97/12542) in view of Tochikubo. Hon teaches a blood pressure measuring apparatus 10 that utilizes an arm board 30 to maintain the wrist of a patient at a posture which can lower the position of at least one tendon of the wrist near the radial artery and cause the radial artery to be close to the radius. In figure 3, the board 30 is shown holding the patient's wrist such that it is flexed but neither parallel nor perpendicular to the forearm; however, any other angle may also be used. The cuff 12, bladder 14, and pressure feeding device 16 work together to apply a changing external pressure to the skin above the radial artery. Sensor 20 detects a pulse wave signal of the radial artery along with a change in the external pressure (figs. 1-3). Hon fails to describe the method of determining blood pressure used.

Tochikubo teaches a blood pressure device comprising an cuff 10 housing a pressure bladder 10d, a pressure feeding-measuring system 24, 20, and 14, and pulse transducer 12. A plurality of optical pulse transducers 12 may be disposed along the circumferential direction, in which case the sensor 12 with the largest output is selected. The device determines minimum and maximum blood pressures from the photoelectric volumetric pulse wave signals and the pressure levels detected by pressure sensor 20 (figs. 1-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method of Tochikubo as the blood pressure determination for the monitoring device of Hon, since Hon specifies that blood pressure is determined, and Tochikubo describes such a method of determining blood pressure. The description of the apparatus inherently discloses the method of using the apparatus.

Claims 1, 2, 6, 12, 14, 17, 21, 22, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon ('542) in view of Aung et al. Hon, as described (figs. 1-3), fails to describe the operation of the blood pressure determining device.

However, Aung describes the operation of an inflatable blood pressure cuff 10 with a pressure feeding-measuring system 12, 14, and 30. Pressure sensor 12 senses a cuff pressure signal SK and a pulse wave signal SM. The CPU 30 determines blood pressures (step S7) using the cuff pressure signal SK and the pulse wave signal SM based on the oscillometric method of blood pressure determination (figs. 1 & 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method of Aung et al. as the blood pressure determination for the monitoring device of Hon, since Hon specifies that blood pressure is determined, and Aung describes such a method of determining blood pressure.

Claims 1, 2, 6, 7, 13, 14, 17, 21, 23, and 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hon ('542) in view of Penáz. Hon, as described (figs. 1-3), fails to describe the operation of the blood pressure determining device. However, Penáz provides a pressure cuff 1, with a plethysmographic gauge 2 of the arterial volume and surrounds the measured zone 3. Gauge 2 connects through a summing member 4 to amplifier 5, which is connected to a voltage-pressure transducer 6. The cuff 1, member 4, amplifier 5, and transducer 6 work together to measure a patient's blood pressure by monitoring the cuff pressure and pulse wave signals according to a vascular unloading method, where the artery volume of the measured zone 3 is maintained at a constant value by immediate pressure changes in the pressure cuff 1. The pressure in cuff 1

corresponds to instantaneous intraarterial pressure when the artery is compressed so that the vascular wall has a zero tension. The gauge 2 utilizes a light source 10 and light sensor 11 on the inner sheet of cuff 1 (figs. 1 & 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method of Penáz as the blood pressure determination for the monitoring device of Hon, since Hon specifies that blood pressure is determined, and Penáz describes such a method of determining blood pressure.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hon ('542) in view of Tochikubo as applied to claims 1, 2, 6-8, 17, 21, and 23 above, and further in view of Chesney et al. Hon ('542), as modified, lacks the arm board has being adapted to cover at least a portion of a dorsal side of a hand, wrist joint, wrist, and forearm, and having several straps attached to the arm board to secure the hand to the board. However Chesney teaches a blood pressure measurement device that utilizes a wrist stabilizer 110 extending over a dorsal side of a hand, wrist joint, wrist and forearm, and having two non-extensible straps 114 and 117 attached to a curved board (figs. 1a-c). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the apparatus of Hon ('542) in view of Tochikubo with that of Chesney in order to further stabilize the radial artery and bring it near the skin in order while holding the patient's hand and fingers in a relaxed position to obtain a good blood-pressure waveform.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hon ('542) in view of Tochikubo and Chesney et al., as applied to claim 18. Hon ('542), as

modified, lacks an increased thickness of the curved arm board in a part adapted to cover the dorsal side of the wrist joint. However, Chesney et al. discloses another embodiment of a wrist stabilizer 900, comprising a curved board where the portion designed to cover a dorsal side of a wrist joint of a user's hand has an increased thickness (fig. 9). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the arm board and blood pressure measuring device of Hon ('542) in view of Tochikubo and Chesney et al. with that of the embodiment of figure 9 of Chesney et al. as a mere matter of design choice because the applicant has not discloses that the increased thickness provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally with or without an increased thickness at the portion of the arm board designed to cover the dorsal side of a wrist joint because the increased thickness is not shown to have any bearing on the blood pressure measurement.

Response to Arguments

Applicant's arguments filed 7/28/03 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The applicant argues that neither the combination of Hon ('542) and Tochikubo nor the combination of Hon ('542) and Aung teaches or suggests keeping a patient's wrist at a posture which can lower a position of at least one tendon of the wrist near a radial artery to be measured and cause the radial artery to be close to a radius of the wrist. Hon shows that the arm board 30 maintains the hand in a position such that the hand is flexed backwards, as shown in figure 3. The applicant discloses that such a position results in lowering the position of the tendon and nerves by the radial artery and causes the radial artery to be placed in a position nearest the radius below it (p.7, lines 15-26, of the instant specification). Therefore, Hon ('542) indeed teaches a method and apparatus in which the wrist is maintained at a posture that can lower the position of at least one tendon near the radial artery and cause the radial artery to be close to the radius. Additionally, the applicant states that the arm board 30 described in Hon can have any angle or no angle at all, and thus does not teach or suggest keeping the patient's wrist at a posture which can lower a position of at least one tendon of the wrist near a radial artery to be measured and cause the radial artery to be close to a radius of the wrist. However, the range from any angle to no angle (p. 9, lines 29-31), taught by Hon, encompasses an angle that achieves the posture which can lower a position of at least one tendon of the wrist near a radial artery to be measured and cause the radial artery to be close to a radius of the wrist.

Finally, the applicant states that there is a difference in the function of the apparatus of Hon ('542) compared to the function of the apparatus and method described by claims 1, 2, and 17 of the instant application. Regardless of the reasons

for the design of the apparatus and method of Hon ('542) in view of Tochikubo or Hon ('542) in view of Aung, the description of the apparatus itself discloses the same elements as those set forth in the rejected claims of the instant application. Similarly the method described by these combinations of references teaches the steps of the method as set forth in the rejected claims of the instant application.

Allowable Subject Matter

Claims 3-5, 10, 11, 15, 16, 19, 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 9, 24-27, and 32 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding the allowability of claims 3-5 and 18, the prior art of record fails to teach or fairly suggest a method or apparatus for measuring blood pressure comprising a step or device for maintaining the wrist at a posture that forms a turning angle of the wrist relative to the forearm attached to the wrist of approximately 30 to 100 degrees toward a medial side of the patient's body (claim 3). The prior art also fails to teach a method or apparatus for measuring blood pressure comprising a step or device for forming a deflecting angle of a central line of the palm of a hand relative to a central line of the volar side of the wrist attached to the hand of 10 to 40 degrees towards the little

finger of the hand (claim 4). Furthermore, the prior art fails to teach a method or device wherein both the above turning angle and deflecting angles are synchronously accomplished or either or both of the above turning angle and deflecting angles are accomplished while synchronously maintaining an angle of 100 to 170 degrees between a dorsal side of the wrist and a dorsal side of the hand (claims 5 and 19).

Regarding the allowability of claim 9, the prior art fails to teach a method of measuring blood pressure having the combination of both keeping the wrist of a patient at a posture that lowers a position of at least one tendon of the wrist near to the radial artery and providing at least 2 columns and 2 rows of measuring sites along directions parallel and vertical to the radial artery, respectively.

Regarding the allowability of claim 10, the prior art fails to teach a method of measuring blood pressure comprising a step of displaying a position of the optimal measuring site within the compressing area of the external pressure.

Regarding the allowability of claim 11, the prior art fails to teach a method of measuring blood pressure comprising a step of automatically checking whether the center of the external pressure corresponds to the optimal measuring site or giving a warning signal when the center of the external pressure does not correspond to the optimal measuring site.

Regarding the allowability of claims 15 and 16, the prior art fails to teach a method of measuring blood pressure comprising the combination of both keeping the wrist at a posture that lowers a position of at least one tendon of the wrist near to the radial artery and applying changing external pressure to an ulnar artery of the wrist or

detecting the pulse wave signal of the ulnar artery so as to measure a blood pressure of the ulnar artery.

Regarding the allowability of claims 24-27, the prior art fails to teach a blood pressure measuring apparatus comprising the combination of a wrist holding device to keep the patient's wrist at a posture that lowers a position of at least one tendon of the wrist near a radial artery and at least two photoelectric devices in a line and a column of the array respectively (a 2x2 array of photoelectric devices). With further regard to claim 27, the prior art additionally fails to teach a warning device that issues a warning signal when a position of the optimal transducer does not correspond to the center of the photoelectric device array.

Regarding the allowability of claim 30, the prior art of record fails to teach a blood pressure measuring apparatus having a pressure feeding-measuring system capable of both intermittently measuring blood pressure according to the oscillometric method and continuously measuring blood pressure according to a vascular unloading method.

Regarding the allowability of claim 31, the prior art fails to teach a blood pressure measuring apparatus comprising the combination of both a wrist holding device to keep the patient's wrist at a posture that lowers a position of at least one tendon of the wrist near a radial artery and two pressure bladders, two pressure transducers, one sensing the pulse wave signal at the radial artery and one at the ulnar artery, and a switching device for switching the two pressure bladders and pulse transducers.

Regarding the allowability of claim 32, the prior art fails to teach a blood pressure measuring device comprising the combination of both a wrist holding device that keeps

a patient's wrist at a posture that lowers the position of at least one tendon of the wrist near a radial artery and a calibrating device for calibrating the measured ulnar artery blood pressure according to the measured radial artery blood pressure.

Conclusion

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Mallari at telephone number (703) 5-0422. The examiner can normally be reached on Mon-Fri 9:30 am-7:00 pm (alternate Fri. off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached at (703) 308-3130. The fax number for the organization where this application or proceeding is assigned is (703) 872-9302.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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ROBERT L. NASSER
PRIMARY EXAMINER